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Celgene Corporation and
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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION and CHILDREN'S MEDICAL CENTER CORPORATION, Plaintiffs, v. LANNETT HOLDINGS, INC. and LANNETT COMPANY, INC., Defendants.	)	Civil Action No. _____ **COMPLAINT** **(Filed Electronically)**

Plaintiffs Celgene Corporation ("Celgene") and Children's Medical Center Corporation ("CMCC") (collectively, "Plaintiffs"), for their Complaint against Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Lannett's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's THALOMID® drug product prior

to the expiration of United States Patent Nos. 6,045,501 (the "'501 patent"), 6,315,720 (the "'720 patent"), 6,561,976 (the "'976 patent"), 6,561,977 (the "'977 patent"), 6,755,784 (the "'784 patent"), 6,869,399 (the "'399 patent"), 7,141,018 (the "'018 patent"), 7,230,012 (the "'012 patent"), 7,435,745 (the "'745 patent"), 7,874,984 (the "'984 patent"), 7,959,566 (the "'566 patent"), 8,204,763 (the "'763 patent"), 8,315,886 (the "'886 patent"), 8,589,188 (the "'188 patent"), and 8,626,531 (the "'531 patent") (collectively, "the patents-in-suit"). The '745 patent is owned by CMCC and exclusively licensed to Celgene. All other patents-in-suit are owned by Celgene.

THE PARTIES

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Plaintiff CMCC is a Massachusetts not-for-profit corporation, having a principal place of business at 55 Shattuck Street, Boston, Massachusetts 02115.

4. On information and belief, Defendant Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 103 Foulk Road, Suite 202, Wilmington, Delaware 19803.

5. On information and belief, Defendant Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 13200 Townsend Road, Philadelphia, Pennsylvania 19154.

6. On information and belief, Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc.

7. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc.

manufacture and/or distribute generic drugs for sale and use throughout the United States, including in this Judicial District. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Lannett Holdings, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Lannett Holdings, Inc. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Lannett Holdings, Inc. has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in New Jersey. On information and belief, Lannett Holdings, Inc. has customers in the State of New Jersey. Further, Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc., which has substantial contacts with the State of New Jersey.

10. This Court has personal jurisdiction over Lannett Company, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Lannett Company, Inc. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Jersey and deriving revenue from such activities. On information and belief, Lannett Company, Inc. has committed, aided, abetted, induced,

contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in New Jersey. On information and belief, Lannett Company, Inc. has customers in the State of New Jersey. Further, on information and belief, Lannett Company, Inc. has previously consented to personal jurisdiction in this Court (*see, e.g.*, Civil Action No. 05-4202), and purposefully availed itself of the benefits of this forum by filing counterclaims in at least one of those actions. Civil Action No. 05-4202.

11. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. operate as an integrated business.

12. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. share common officers and directors and are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in New Jersey.

13. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. together formulate, develop, market, and sell active pharmaceutical ingredients ("APIs"), solid dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations that they distribute in New Jersey and throughout the United States.

14. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. together routinely file, and/or aid, abet, contribute to, and/or participate in the filing of, ANDAs to seek FDA approval to market their products in the United States, including in New Jersey.

15. On information and belief, Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc. On information and belief, Lannett Company, Inc., acting either alone or in concert with Lannett Holdings, Inc., either directly or through one or more of its

subsidiaries, agents, and/or distributors, markets, sells, and/or distributes pharmaceutical products in New Jersey.

16. On information and belief, Lannett Company, Inc. directs, authorizes, cooperates, participates, and/or assists Lannett Holdings, Inc. with the marketing, selling, and/or distributing pharmaceutical products in New Jersey. On information and belief, the acts of Lannett Holdings, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Lannett Company, Inc.

17. On information and belief, this Judicial District is a likely destination of products that will be manufactured and sold as a result of FDA approval of Lannett's ANDA No. 206-601, which is the subject of this lawsuit.

18. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. have committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs including Celgene Corporation, which has its principal place of business in New Jersey.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

20. On April 4, 2000, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '501 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '501 patent is attached hereto as Exhibit A.

21. On November 13, 2001, the USPTO duly and lawfully issued the '720 patent,

entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '720 patent is attached hereto as Exhibit B.

22. On May 13, 2003, the USPTO duly and lawfully issued the '976 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '976 patent is attached hereto as Exhibit C.

23. On May 13, 2003, the USPTO duly and lawfully issued the '977 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '977 patent is attached hereto as Exhibit D.

24. On June 29, 2004, the USPTO duly and lawfully issued the '784 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On May 3, 2005, a certificate of correction was granted by the USPTO to correct a typographical error in claim 29 of the '784 patent. A copy of the '784 patent and its certificate of correction are attached hereto as Exhibit E.

25. On March 22, 2005, the USPTO duly and lawfully issued the '399 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On March 7, 2006, a certificate of correction was granted by the USPTO to correct typographical errors in claim 19 of the '399 patent. A copy of

the ’399 patent and its certificate of correction is attached hereto as Exhibit F.

26. On November 28, 2006, the USPTO duly and lawfully issued the ’018 patent, entitled “Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated” to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the ’018 patent is attached hereto as Exhibit G.

27. On June 12, 2007, the USPTO duly and lawfully issued the ’012 patent, entitled “Pharmaceutical Compositions and Dosage Forms of Thalidomide” to Celgene as assignee of the inventors Paul D’Angio and John McCarty. A copy of the ’012 patent is attached hereto as Exhibit H.

28. On October 14, 2008, the USPTO duly and lawfully issued the ’745 patent, entitled “Methods and Compositions for Inhibition of Angiogenesis,” to CMCC as assignee of the inventor Robert J. D’Amato. The ’745 patent is licensed exclusively to Celgene. On April 7, 2009, a certificate of correction was granted by the USPTO to correct the name of the assignee from Celgene to CMCC. A copy of the ’745 patent and its certificate of correction is attached hereto as Exhibit I.

29. On January 25, 2011, the USPTO duly and lawfully issued the ’984 patent, entitled “Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug” to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the ’984 patent is attached hereto as Exhibit J.

30. On June 14, 2011, the USPTO duly and lawfully issued the ’566 patent, entitled “Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated” to Celgene as assignee of the inventors Bruce A.

Williams and Joseph K. Kaminski. A copy of the '566 patent is attached hereto as Exhibit K.

31. On June 19, 2012, the USPTO duly and lawfully issued the '763 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '763 patent is attached hereto as Exhibit L.

32. On November 20, 2012, the USPTO duly and lawfully issued the '886 patent, entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '886 patent is attached hereto as Exhibit M.

33. On November 19, 2013, the USPTO duly and lawfully issued the '188 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '188 patent is attached hereto as Exhibit N.

34. On January 7, 2014, the USPTO duly and lawfully issued the '531 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '531 patent is attached hereto as Exhibit O.

THE THALOMID® DRUG PRODUCT

35. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for thalidomide capsules (NDA No. 20-785), which it sells under the trade name THALOMID®. The

claims of the patents-in-suit cover, *inter alia*, methods of use and delivery of pharmaceutical compositions containing the drug thalidomide.

36. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to THALOMID®.

ACTS GIVING RISE TO THIS ACTION

37. Pursuant to Section 505 of the FFDCA, Lannett filed ANDA No. 206-601 ("Lannett's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of thalidomide capsules 50 mg, 100 mg, 150 mg, and 200 mg ("Lannett's Proposed Products"), before the patents-in-suit expire.

38. In connection with the filing of its ANDA as described in the preceding paragraph, Lannett has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Lannett's ANDA.

39. On or about December 22, 2014, Plaintiffs received written notice of Lannett's ANDA certification ("Lannett's Notice Letter"). Lannett's Notice Letter alleged that the claims of the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Lannett's ANDA. Lannett's Notice Letter also informed Plaintiffs that Lannett seeks approval to market Lannett's Proposed Products before the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents expire.

COUNT I: INFRINGEMENT OF THE '501 PATENT

40. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if

fully set forth herein.

41. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '501 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

42. There is a justiciable controversy between the parties hereto as to the infringement of the '501 patent.

43. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '501 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

44. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '501 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '501 patent and knowledge that its acts are encouraging infringement.

45. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '501 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '501 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

46. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's

infringement of the ’501 patent is not enjoined.

47. Plaintiffs do not have an adequate remedy at law.

48. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE ’720 PATENT

49. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

50. Lannett’s submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the ’720 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

51. There is a justiciable controversy between the parties hereto as to the infringement of the ’720 patent.

52. Unless enjoined by this Court, upon FDA approval of Lannett’s ANDA, Lannett will infringe the ’720 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett’s Proposed Products in the United States.

53. Unless enjoined by this Court, upon FDA approval of Lannett’s ANDA, Lannett will induce infringement of the ’720 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett’s Proposed Products in the United States. On information and belief, upon FDA approval of Lannett’s ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the ’720 patent and knowledge that its acts are encouraging infringement.

54. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '720 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '720 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

55. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '720 patent is not enjoined.

56. Plaintiffs do not have an adequate remedy at law.

57. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '976 PATENT

58. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

59. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

60. There is a justiciable controversy between the parties hereto as to the infringement of the '976 patent.

61. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '976 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

62. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '976 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '976 patent and knowledge that its acts are encouraging infringement.

63. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '976 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '976 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

64. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '976 patent is not enjoined.

65. Plaintiffs do not have an adequate remedy at law.

66. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '977 PATENT

67. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

68. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '977 patent, constitutes infringement of one or more

of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

69. There is a justiciable controversy between the parties hereto as to the infringement of the '977 patent.

70. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '977 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

71. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '977 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '977 patent and knowledge that its acts are encouraging infringement.

72. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '977 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '977 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

73. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '977 patent is not enjoined.

74. Plaintiffs do not have an adequate remedy at law.

75. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE '784 PATENT

76. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

77. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '784 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

78. There is a justiciable controversy between the parties hereto as to the infringement of the '784 patent.

79. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '784 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

80. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '784 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '784 patent and knowledge that its acts are encouraging infringement.

81. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '784 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that

Lannett's Proposed Products are especially adapted for a use that infringes the '784 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

82. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '784 patent is not enjoined.

83. Plaintiffs do not have an adequate remedy at law.

84. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF THE '399 PATENT

85. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

86. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '399 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

87. There is a justiciable controversy between the parties hereto as to the infringement of the '399 patent.

88. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '399 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

89. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '399 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will

intentionally encourage acts of direct infringement with knowledge of the '399 patent and knowledge that its acts are encouraging infringement.

90. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '399 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '399 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

91. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '399 patent is not enjoined.

92. Plaintiffs do not have an adequate remedy at law.

93. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VII: INFRINGEMENT OF THE '018 PATENT

94. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

95. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '018 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

96. There is a justiciable controversy between the parties hereto as to the infringement of the '018 patent.

97. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett

will infringe the '018 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

98. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '018 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '018 patent and knowledge that its acts are encouraging infringement.

99. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '018 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '018 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

100. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '018 patent is not enjoined.

101. Plaintiffs do not have an adequate remedy at law.

102. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII: INFRINGEMENT OF THE '012 PATENT

103. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

104. Lannett's submission of its ANDA to obtain approval to engage in the

commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '012 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

105. There is a justiciable controversy between the parties hereto as to the infringement of the '012 patent.

106. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '012 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

107. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '012 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '012 patent and knowledge that its acts are encouraging infringement.

108. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '012 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '012 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

109. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '012 patent is not enjoined.

110. Plaintiffs do not have an adequate remedy at law.

111. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IX: INFRINGEMENT OF THE '745 PATENT

112. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

113. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '745 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

114. There is a justiciable controversy between the parties hereto as to the infringement of the '745 patent.

115. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '745 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

116. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '745 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '745 patent and knowledge that its acts are encouraging infringement.

117. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '745 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United

States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '745 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

118. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '745 patent is not enjoined.

119. Plaintiffs do not have an adequate remedy at law.

120. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT X: INFRINGEMENT OF THE '984 PATENT

121. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

122. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '984 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

123. There is a justiciable controversy between the parties hereto as to the infringement of the '984 patent.

124. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '984 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

125. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '984 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United

States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '984 patent and knowledge that its acts are encouraging infringement.

126. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '984 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '984 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

127. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '984 patent is not enjoined.

128. Plaintiffs do not have an adequate remedy at law.

129. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XI: INFRINGEMENT OF THE '566 PATENT

130. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

131. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '566 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

132. There is a justiciable controversy between the parties hereto as to the infringement of the '566 patent.

133. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '566 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

134. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '566 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '566 patent and knowledge that its acts are encouraging infringement.

135. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '566 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '566 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

136. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '566 patent is not enjoined.

137. Plaintiffs do not have an adequate remedy at law.

138. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XII: INFRINGEMENT OF THE '763 PATENT

139. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

140. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '763 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

141. There is a justiciable controversy between the parties hereto as to the infringement of the '763 patent.

142. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '763 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

143. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '763 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '763 patent and knowledge that its acts are encouraging infringement.

144. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '763 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '763 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

145. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '763 patent is not enjoined.

146. Plaintiffs do not have an adequate remedy at law.

147. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIII: INFRINGEMENT OF THE '886 PATENT

148. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

149. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '886 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

150. There is a justiciable controversy between the parties hereto as to the infringement of the '886 patent.

151. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '886 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

152. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '886 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '886 patent and knowledge that its acts are encouraging infringement.

153. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '886 patent under 35 U.S.C. § 271(c) by making, using, offering

to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '886 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

154. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '886 patent is not enjoined.

155. Plaintiffs do not have an adequate remedy at law.

156. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIV: INFRINGEMENT OF THE '188 PATENT

157. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

158. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '188 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

159. There is a justiciable controversy between the parties hereto as to the infringement of the '188 patent.

160. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will infringe the '188 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States.

161. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will induce infringement of the '188 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, upon FDA approval of Lannett's ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the '188 patent and knowledge that its acts are encouraging infringement.

162. Unless enjoined by this Court, upon FDA approval of Lannett's ANDA, Lannett will contributorily infringe the '188 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett's Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett's Proposed Products are especially adapted for a use that infringes the '188 patent and that there is no substantial noninfringing use for Lannett's Proposed Products.

163. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett's infringement of the '188 patent is not enjoined.

164. Plaintiffs do not have an adequate remedy at law.

165. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XV: INFRINGEMENT OF THE '531 PATENT

166. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

167. Lannett's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules into the United States, prior to the expiration of the '531 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

168. There is a justiciable controversy between the parties hereto as to the

infringement of the ’531 patent.

169. Unless enjoined by this Court, upon FDA approval of Lannett’s ANDA, Lannett will infringe the ’531 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Lannett’s Proposed Products in the United States.

170. Unless enjoined by this Court, upon FDA approval of Lannett’s ANDA, Lannett will induce infringement of the ’531 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Lannett’s Proposed Products in the United States. On information and belief, upon FDA approval of Lannett’s ANDA, Lannett will intentionally encourage acts of direct infringement with knowledge of the ’531 patent and knowledge that its acts are encouraging infringement.

171. Unless enjoined by this Court, upon FDA approval of Lannett’s ANDA, Lannett will contributorily infringe the ’531 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lannett’s Proposed Products in the United States. On information and belief, Lannett has had and continues to have knowledge that Lannett’s Proposed Products are especially adapted for a use that infringes the ’531 patent and that there is no substantial noninfringing use for Lannett’s Proposed Products.

172. Plaintiffs will be substantially and irreparably damaged and harmed if Lannett’s infringement of the ’531 patent is not enjoined.

173. Plaintiffs do not have an adequate remedy at law.

174. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Lannett has infringed the ’501, ’720, ’976, ’977, ’784, ’399, ’018, ’012, ’745, ’984, ’566, ’763, ’886, ’188, and ’531 patents by submitting ANDA No. 206-601;

(B) A Judgment be entered that Lannett has infringed, and that Lannett’s making, using, selling, offering to sell, or importing into the United States Lannett’s Proposed Products will infringe one or more claims of the ’501, ’720, ’976, ’977, ’784, ’399, ’018, ’012, ’745, ’984, ’566, ’763, ’886, ’188, and ’531 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 206-601 be a date which is not earlier than the later of the expiration of the ’501, ’720, ’976, ’977, ’784, ’399, ’018, ’012, ’745, ’984, ’566, ’763, ’886, ’188, and ’531 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Lannett and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Lannett’s Proposed Products until after the expiration of the ’501, ’720, ’976, ’977, ’784, ’399, ’018, ’012, ’745, ’984, ’566, ’763, ’886, ’188, and ’531 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lannett, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any systems or methods as claimed in the ’501, ’720, ’976, ’977, ’784, ’399, ’018, ’012, ’745, ’984, ’566, ’763, ’886, ’188, and ’531

patents, or from actively inducing or contributing to the infringement of any claim of any of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Lannett's Proposed Products will directly infringe, induce, and/or contribute to infringement of the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents;

(G) To the extent that Lannett has committed any acts with respect to the inventions claimed in the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Lannett engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Lannett's Proposed Products prior to the expiration of the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) A Judgment declaring that the '501, '720, '976, '977, '784, '399, '018, '012, '745, '984, '566, '763, '886, '188, and '531 patents remain valid and enforceable;

(J) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(K) Costs and expenses in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: January 30, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, Celgene Corporation, six of the same patents that are at issue in the matter captioned *Celgene Corporation v. Natco Pharma Limited, et al.*, Civil Action No. 10-5197 (SDW)(SCM), and two of the same patents that are at issue in the matter captioned *Celgene Corporation v. Natco Pharma Limited, et al.*, Civil Action No. 14-3126 (SDW)(SCM).

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 30, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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